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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/282,879 | 03/31/99 | CHATTERJEE | S 46906-2-DIV |

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HM22/1003

EXAMINER

RAO, M

ART UNIT PAPER NUMBER

1652

DATE MAILED:

10/03/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-------------------------------|-----------------------------------|
| Office Action Summary | Application No. 09/282,879 | Applicant(s) Chatterjee et al. |
| | Examiner Manjunath N. Rao | Group Art Unit 1652 |

Responsive to communication(s) filed on Mar 31, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 13-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 13-30 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 13-17, drawn to methods of using human neutral sphingomyelinase to identify compounds that interact with it, classified in class 435, subclass 18.
 - II. Claims 18-20, drawn to an isolated human neutral sphingomyelinase, classified in class 435, subclass 196.
 - III. Claims 21, 24-24, drawn to method of modulating the activity of human neutral sphingomyelinase using nucleic acids, classified in class 514, subclass 44.
 - IV. Claims 22, 25-26, drawn to method of modulating the activity of human neutral sphingomyelinase, classified in class 424, subclass 94.6.
 - V. Claims 27-29, drawn to sperm and seminal fluid samples comprising human neutral sphingomyelinase as well as methods of maintaining the samples, classified in class 435, subclass 2.
 - VI. Claim 30, drawn to methods to reduce apoptosis by administration of antibodies against human neutral sphingomyelinase, classified in class 424, subclass 130.1.
2. The inventions are distinct, each from the other because of the following reasons:

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3. Inventions I, III, IV-VI are patentably distinct from each other. The method to identify compounds interacting with sphingomyelinase of Group I, the method of modulating the expression of sphingomyelinase of group III, the methods of modulating the activity of sphingomyelinase of group IV, the samples and maintenance methods of Group V and the method of reducing apoptosis of Group VI comprise separate and distinct steps, utilize separate compounds and produce separate results. They do not require each other for their practice and are subject to separate manufacture and sale. The Groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

4. Invention II and I, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the enzyme of group II can be used in a materially different process of making antibodies as opposed to its use in the methods of Groups I, IV and V.

7. Inventions II, III and VI are patentably distinct from each other. The enzyme of group II, the gene therapy method of group III and the method of reducing apoptosis of group VI do not require each other for practice; have separate utilities, such as the enzyme of group II to catalyze a sphingomyelinase reaction, versus the use of methods of group III and VI; and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

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8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. A telephone call was made to Peter Corless on 10-2-2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Manjunath N. Rao

October 2, 2000